Case: 1:10-cv-00224-JG Doc #: 1 Filed: 02/02/10 1 of 27. PageID #: 1

UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF OHIO EASTERN DIVISION

No.

GEORGE MCKINNEY, On Behalf of Himself and All Others Similarly Situated

JUDGE

Plaintiff,

CLASS ACTION COMPLAINT

v.
BAYER CORPORATION, BAYER
HEALTHCARE LLC, and DOES 1-10.

Jury Demand Endorsed Hereon

Defendant.

- 1. Plaintiff, George McKinney, by and through his attorneys, brings this Class Action Complaint on behalf of himself and other similarly situated persons against Defendants, Bayer Corporation and Bayer Healthcare LLC (collectively "Defendants" or "Bayer"). Defendants advertise that their vitamins promote prostate health, when in fact, they do not. Instead, studies strongly suggest that the ingredient Bayer claims provides this health benefit, a chemical element known as "selenium," actually poses serious health risks when taken in the amounts recommended by Bayer. Plaintiff was exposed to the false, misleading and deceptive claims, relied upon said claims and has been damaged and otherwise suffered harm because he paid for Vitamin Products (as defined below) that were falsely advertised.
- 2. In about 2002, Bayer introduced vitamin products aimed at men over the age of 50, claiming these specially tailored vitamins will provide prostate-related health benefits

because they contained selenium. The vitamins are brand named "One A Day Men's Health Formula" and "One A Day Men's 50+ Advantage" (collectively the "Vitamin Products"). Bayer promises that these vitamins will "support prostate health" and "reduce the risk of prostate cancer" ("Prostate Claims"). Bayer's misrepresentations appear on each label of the Vitamin Products and were widely disseminated on websites, in print media, on television, point of purchase signs, and through other advertising medium.

- 3. As more fully described herein, Bayer's Vitamin Product advertisements, including its labels, are unlawful, unfair, fraudulent, and unconscionable within the meaning of Ohio's Sales Practice Act, Ohio's Deceptive Trade Practices Act, The Ohio Revised Code and Ohio's Consumer Law.
- 4. The selenium in the Vitamin Products neither supports prostate health nor reduces the risk of prostate cancer. Bayer does not possess a single proper scientific or clinical study which demonstrates that the Vitamin Products support prostate health or reduce the risk of prostate cancer. In fact, as recent as June 19, 2009, the "FDA concluded[d] that it is highly unlikely that selenium reduce[s] the risk of prostate cancer..."
- 5. Instead, the selenium in the Vitamin Products may actually cause harm promote, rather than reduce prostate cancer. Specifically, research indicates that men with prostate cancer and high blood levels of selenium may have an *increased risk of aggressive* prostate cancer. In addition, selenium supplements such as those found in the Vitamin Products may *increase the risk for diabetes*.
- 6. Bayer's Vitamin Products contain sodium selenate, an inorganic form of selenium.

- 7. In fact, as reported by the FDA on June 19, 2009, any scientific support for claims that selenium may reduce the risk of prostate cancer is limited to studies that used serum or plasma selenium as a biomarker of intake and reflected an intake of selenomethionine, not intake of selenocysteine or inorganic forms of selenium such as selenate (the inorganic form contained in the Vitamin Products) and selenite.
- 8. Despite the fact that there is no substantiation for the Prostate Claims, Bayer's claims remain on the labels of boxes recently for sale. As recently as October 5, 2009 the advertising and labeling for Bayer's Vitamin Products contained the unlawful and deceptive Prostate Claims.
- 9. For the reasons stated herein, the Court should declare that Bayer's Prostate Claims are actions that are unlawful and unfair within the meaning of Ohio's Consumer Sales Practice Act, Ohio's Deceptive Trade Practices Act and constitute a Breach of Express and Implied Warranties, and enjoin Bayer from making such Prostate Claims in the future. Plaintiff and Class members are also entitled to refunds of the purchase price of the Vitamin Products.

JURISDICATION AND VENUE

- 10. This Court has original jurisdiction pursuant to 28 U.S.C. § 1332(d)(2). The matter in controversy, exclusive of interest and costs, exceeds the sum of value of \$5,000,000 and is a class action in which members of the Class are citizens of different states different from Defendants. Further, greater than two-thirds of the Class members reside in states other than the state in which Defendants are citizens.
- 11. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 in that many of the acts and transactions giving rise to this action occurred in this District because Defendants:

- (a) are authorized to conduct business in this District and have intentionally availed themselves of the laws and markets within this District through the promotion, marketing, distribution and sale of their products in this District;
 - (b) do substantial business in this District; and
 - (c) are subject to personal jurisdiction in this District.

DESCRIPTION OF THE PARTIES TO THIS ACTION

- 12. At all times relevant to this matter, Plaintiff, George McKinney, resided and continues to reside in the Northern District of Ohio, Eastern Division.
- 13. Plaintiff brings this action on behalf of himself and other similarly situated consumers in Ohio to enjoin and correct Bayer's false and misleading promotion of the Vitamin Products, as more fully described herein, and to obtain legal relief for those who have purchased the Vitamin Products from the Defendant.
- 14. Plaintiff has relied on the false claims concerning the Vitamin Products and has lost money and incurred damages as a result of Defendants' false and misleading advertising, packaging and deceptive trade practices as more fully described herein.
- 15. Defendant Bayer Corporation is organized and incorporated in the State of Indiana with its principle place of business at 100 Bayer Road, Pittsburgh, Pennsylvania.
- 16. Bayer HealthCare LLC is a limited liability corporation organized under the laws of the State of Delaware, with its principal place of business at 555 White Plains Road, Tarrytown, New York 10591. This Complaint jointly refers to both defendants as "Bayer," in the singular, unless the context demands otherwise.
- 17. Defendant Does 1-10 are other persons or entities, whose names are currently unknown to Plaintiff despite diligent efforts to identify them, who participated in, assisted in

and/or committed the torts alleged against Bayer in this action. When the actual names of such individuals or entities become known, Plaintiff will promptly take steps to name them in this action.

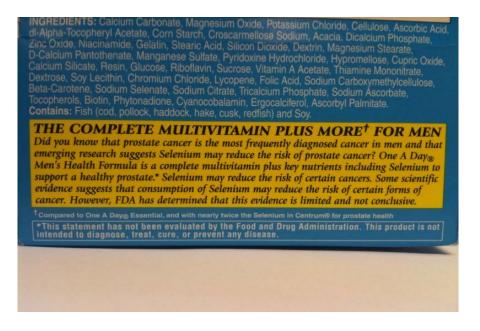
- 18. At all relevant times, both Defendants, and each of them, were acting within the scope and course of their authority and with the permission and consent of the other Defendant. Defendants engaged in the misconduct alleged herein for the purpose of enriching themselves at the expense of Plaintiff.
- 19. Bayer is organized and registered to do business in the State of Ohio and does business in the State of Ohio.
 - 20. Bayer is a wholly owned subsidiary of Bayer AG, Germany.
- 21. Bayer advertises and sells its Vitamin Products throughout the United States, including Ohio, including brands known as Men's One A Day Health Formula and Men's One A Day +50 Health Formula.
- 22. The Plaintiff alleges violations of the Ohio Consumer Sales Practice Act, the Ohio Deceptive Trade Practices Act, and breach of express warranty created by Bayer's promotions, advertising and labeling.
- 23. At all times relevant, Plaintiff heard, saw and relied upon the Prostate Claims made by Bayer in its various promotions, commercials, advertisements and Vitamin Product labels.
- 24. In reliance on the representations made in said promotions, commercials, advertisements and product labels, Plaintiff purchased each of the Bayer Vitamin Products and has been damaged in that Plaintiff did not receive the Vitamin Product as advertised and warranted and containing the claimed health benefits.

FACTUAL ALLEGATIONS IN SUPPORT OF PLAINTIFF'S COMPLAINT

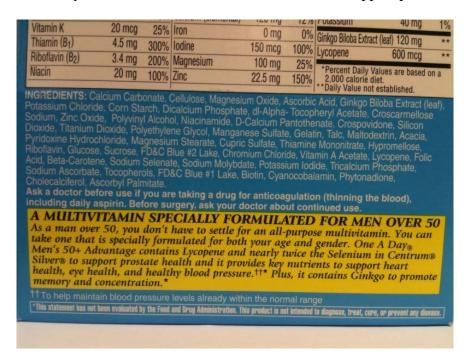
- 25. Bayer has promoted its Vitamin Products for the mitigation, prevention, treatment, or cure of prostate cancer on package labels, on its website, in television and radio advertisements, and through other medium. Since 2008, Bayer has run at least eleven versions of television advertisements and at least nine versions of radio advertisements repeating the same misrepresentations.
- 26. Through its commercials, advertisements, websites and labels, Bayer states, among other things, that "recent research suggests that Selenium" contained in the Men's Ones A Day Health "may reduce the risk of developing prostate cancer." Bayer uses the name "Selenium" and claims that it prevents prostate cancer in order to deceive the buying public into believing their multivitamin has some defensive properties because it contains selenium.
- 27. The label on each package of Men's One A Day Health Formula prominently makes the Prostate Claims as follows:



28. The Prostate Claims are also on the back of the package labels. For example, on the back of the package for Men's One A Day Health Formula, Bayer states: "Did you know that prostate cancer is the most frequently diagnosed cancer in men and that emerging research suggests Selenium may reduce the risk of prostate cancer?"



29. Similarly, the back of the package label for One A Day Men's 50+ Advantage states it contains "nearly twice the Selenium in Centrum Silver to support prostate health."



30. Bayer's television and radio advertisements make substantially similar Prostate Claims. For example, one of the radio advertisements claimed:

Prostate cancer. It's an important subject. Did you know that there are more new cases of prostate cancer each year than any other cancer? And here's something else you should know. Now, there's something you can do that may help reduce your risk. Along with your regular doctor checkups, switch to One A Day Men's. A complete multivitamin plus selenium, which emerging research suggests may help reduce the risk of prostate cancer. One A Day Men's. Because staying healthy is serious business.

31. Bayer's television commercials make similar claims. For example, a television commercial for One A Day Men's Health Formula represented:

Did you know one in three men will face prostate issues? One in three, really? That's why One A Day Men's is a complete multivitamin with selenium which emerging research suggests can help prostate health. One A Day Men's.

32. Bayer ran a television commercial for One A Day Men's 50+ Advantage that said:

To stay on top of my game after 50, I switched to a complete multivitamin with more. Only One A Day Men's 50+ Advantage has gingko for memory and concentration plus support for prostate and heart health. Safe. That's a great call. One A Day Men's.

- 33. Bayer's website repeats the Prostate Claims: "Did you know that 1 in 6 men will face prostate issues? Prostate cancer is the most frequently diagnosed non-skin cancer in men, and emerging research suggests Selenium may reduce the risk of prostate cancer."
- 34. Plaintiff has seen and heard television and radio commercials making the Prostate Claims.
- 35. Scientific research does not substantiate Bayer's Prostate Claims, including the claims that selenium or the Vitamin Products reduce the risk of prostate cancer and

support prostate health. To the contrary, the research shows the amount of selenium in the Vitamin Products may be harmful.

- 36. There have been two randomized controlled trials of selenium supplementation for the prevention of prostate cancer—The Nutritional Prevention of Cancer ("NPC") trial and the federally funded Selenium and Vitamin E Cancer Prevention Trial ("SELECT")
- 37. The vast majority of men in the NPC trial received no benefit at all from the selenium supplementation.¹
- 38. Of significant concern, the NPC trial found nearly a three-fold increased risk of self-reported diabetes in men who were assigned to take 200 micrograms of selenium and who had the highest levels of blood selenium at the start of the trial.²
- 39. In response to the finding, the American College of Physicians issued a summary for patients stating:

Selenium supplements appear to *increase the risk for diabetes*. Although the findings need to be confirmed, long-term selenium supplementation should not be viewed as harmless and possibly healthy way to prevent illness.³

40. In October 2008 the National Cancer Institute abruptly terminated the SELECT trial, the largest prostate cancer prevention trial ever undertaken, because "selenium and vitamin E supplements taken alone or together, did not prevent prostate cancer" and

¹ BJU International 2003; 91: 608-612.

² Ann. Intern Med 2007; 147: 217-23.

³ Ann. Intern Med 2007; 147: 1-14 [emphasis added].

⁴ http://www.cancer.gov/newscenter/pressreleases/SELECTJAMAresults2008. There was also the concern that "a small but not statistically significant increase in the number of prostate cancer cases among the over 35,000 men age 50 and older in the trial taking only vitamin E."

because of "a small, but not statistically significant increase in the number of cases of adult onset diabetes in men taking only selenium." In fact, the increased risk of diabetes just missed statistical significance (p=.08 per interim data of August 1, 2008.)⁵

- 41. As a result of the previous selenium trial, in which there was a three-fold increased risk in the number of self-reported diabetes, the SELECT data and the safety monitoring committee "had some concern" about selenium⁶. The National Cancer Institute called the findings a "concerning" trend.⁷
- 42. The authors of the SELECT trial concluded that it "has definitely demonstrated that selenium, vitamin E, or selenium + vitamin E (at the tested doses and formulations) did not prevent prostate cancer in a generally healthy, heterogeneous population of the men in SELECT."
- 43. An editorial in the Journal of the American Medical Association accompanying publication of the SELECT results concluded that "physicians should not recommend selenium or vitamin E—or any other antioxidant supplements—to their patients for preventing prostate cancer."
- 44. In their letter to the FTC on June 18, 2009, nine prominent cancer researchers stated that the SELECT trial:

[P]roduced strong evidence last October that selenium does not prevent prostate cancer in a generally healthy, heterogeneous population of the men in the United States and Canada. This Federally-financed study

⁵ JAMA 2009; 301: 39-51.

⁶ JAMA 2009; 301: 39-51.

⁷ http://www.cancer.gov/clinicaltrials/digestpage/SELECT.

⁸ JAMA 2009; 301: 39-51 [emphasis added].

⁹ JAMA 2009; 301: 102-3 [emphasis added].

was the largest individually randomized cancer prevention trial ever conducted, and, given its high rates of adherence and statistical power, it's unlikely to have had missed detecting a benefit of even a very modest size. Bayer Healthcare is doing a disservice to men by misleading them about a protective role for selenium in prostate cancer. We ask that you take whatever steps are necessary to halt these ads as soon as possible. 10

- 45. These are not the only studies showing the failure of selenium to prevent prostate cancer. June M. Chan of the University of California at San Francisco and her colleagues at the Dana-Farber Cancer Institute, the Harvard Medical School, and the Fred Hutchinson Cancer Research Center found in their study of plasma selenium and manganese superoxide dismutase (SOD2) genotypes in men with prostate cancer that men with high blood levels of selenium who carried the V allele had a more than two-fold increased risk(RR=2.48) of presenting with aggressive prostate cancer, a finding that was statistically significant. An allele is, in basic terms, a unique form of a single gene. About 75% of men carry the V allele.
- 46. They concluded that "for the 75% [of] men who carry the V allele, higher selenium levels might increase the likelihood of having worst tumor characteristics." They cautioned "against broad use of selenium for men with prostate cancer." ¹¹
- 47. In fact, Philip Kantoff, M.D., director of Dana Farbers Lank Center for Genitourinary Oncology and senior author of the study, said that "if you already have prostate cancer, it may be a bad thing to take selenium...There is some precedent to this

¹⁰ http://cspinet.org/new/pdf/bayer-ftc-letter-scientists.pdf [emphasis added]

¹¹ J Clin Oncol 2009; 27: 3577-83.

[since] research has suggested that antioxidants could be protective if you don't have cancer, but once you do, then antioxidants may be a bad thing."¹²

- 48. This study involved an ongoing cohort of men diagnosed with prostate cancer who donated blood for research before undergoing any type of local therapy and who consented to clinical research follow-up. The researchers concluded that it provided, "strong support for the hypothesis that plasma selenium levels and SOD2 genotype interact to influence risk of presenting with aggressive prostate cancer at diagnosis in men with localized or locally advanced prostate cancer."
- 49. Despite Bayer's attempts to characterize the above study as unexpected and unprecedented, the authors stated in their discussion of the results that data from previous studies indicated that higher doses of selenium could have adverse effects. And while they could not exclude the possibility that men with worse clinical features were taking extra selenium, they went on to say that this was unlikely, in part because the blood was donated shortly after diagnosis.
- 50. Yet another recent study announced April 26, 2009, at the annual meeting of the American Urological Association (AUA) showed that selenium failed to prevent the development of prostate problems.
- 51. In a three-year trial funded by the Nation Cancer Institute and the Ontario Institute of Cancer Research, men with precancerous lesions in the prostate called high-grade prostatic intraepithelial neoplasia who received a daily supplement of 200 micrograms of

¹² http://www.dana-farber.org/abo/news/press/2009/selenium-intake-may-worsen-prostate-cancer-in-some-study-reports.html.

selenium, 40 grams of soy protein, and 800 IU of vitamins were just as likely to develop invasive prostate cancer as men who received a placebo.¹³

- 52. Christopher Amling, M.D. an AUA spokesman, stated that, "[u]nfortunately, as this study shows, we have yet to find a dietary supplement that will reliably prevent prostate cancer." Dr. Amling also concluded that "[t]he results of this study support the findings of the SELECT trial which also demonstrated no benefit using Vitamin E and selenium. These studies highlight the importance of conducting randomized trials of these agents since many of these supplements are promoted falsely to the general public as having beneficial effects on cancer prevention and progression." 14
- 53. Reacting to the results of the Canadian Study, lead researcher Dr. Neil E. Fleshner, a Clinical Studies Resource Centre Member at the Ontario Cancer Institute and Love Chair in Prostate Cancer Prevention at the University of Toronto, stated: "There was great hope that this would be a magic bullet that would help prevent prostate cancer...Unfortunately it doesn't appear to be so."
- 54. The cumulative evidence thus shows that, rather than ensuring that its marketing claims were substantiated by scientific proof, Bayer has ignored the overwhelming scientific data on selenium and continues to make its unsubstantiated and illegal claims.
- 55. On November 17, 2009, Plaintiff sent Bayer a notice of intent to sue for its false and deceptive Vitamin Products' marketing. Plaintiff's notice of intent references the Ohio laws that form the basis of this lawsuit, and states Plaintiff's intent to file a lawsuit

¹³ Journal of Urology 2009; 181 (4 Suppl): 263.

¹⁴ http://www.auanet.org/content/press/press_releases/article.cfm?articleNo=115 [emphasis added]

¹⁵ http://www.healthyontario.com/NewsItemDetails.aspx?newsitem_id=1616. Accessed September 28, 2009.

¹⁶ Plaintiff's Letter to Bayer, November 17, 2009 (attached as Exhibit 1).

against Bayer for fraudulent and deceptive practices in marketing and sale of Bayer's Vitamin Products.

- 56. Bayer has been caught in illegal behavior many times in the past, including:
 - a. In 2001, Bayer paid \$14 million to U.S. and state governments to settle allegations that the company's actions helped healthcare providers submit inflated Medicaid claims for drugs.¹⁷
 - b. In 2003, Bayer pleaded guilty to a criminal charge and paid \$257 million in fines and penalties after a whistleblower exposed a scheme by the company to overcharge for the antibiotic Cipro. Media accounts at the time described it as the biggest recovery of Medicaid fraud.
 - c. In 2004, Bayer pleaded guilty to a criminal charge and paid a \$66 million fine after a Justice Department investigation into Bayer's role in a price fixing conspiracy involving a chemical used to make rubber products.¹⁹ Two Bayer executives separately pleaded guilty and were also sentenced to prison for their role in the scandal.
 - d. In 2007, Bayer paid \$8 million to resolve allegations by state attorneys general that the company failed to warn physicians and consumers about safety issues surrounding its cholesterol-lowering drug called Baycol, which is no longer on the market.²⁰
 - e. In 2007, Bayer was fined 3.2 million dollars by the FTC for claims of weight loss from the One a Day weight smart brand that were also false. The Bayer Company is currently running a corrective advertising campaign at the behest of the FDA on another one of its products the YAZ birth control pill. In both instances, Bayer made deceptive and exaggerated claims on the benefits of these products while downplaying and glazing over the negative effects and health risks of these products.

¹⁷ www.nytimes.com/2001/01/24/us/bayer-to-pay-14-million-to-settle-charges-of-causing-inflated-medicaid-claims.html.

¹⁸ www.nvtimes.com/2003/04/17/business/17DRUG.html.

¹⁹ www.osdoj.gov/atr/public/press releases/2004/204602.htm.

 $^{^{20}\} www.ksag.org/page/attorney-general-morrison-announces-30-state-settlement-with-bayer-corporation.$

²¹ www.ftc.gov/opa/2007/01/weightloss.shtm.

- f. This year Bayer was required to run a \$20-million dollar corrective advertising campaign about its birth control pill Yaz, and to submit its ads to the FDA for approval.²²
- 57. Bayer says that "emerging research" shows that selenium may prevent prostate cancer. Although it does not provide scientific or clinical substantiation, a study conducted by the Nutritional Prevention of Cancer Trial in 1996 "unexpectedly" found that selenium seemed to prevent men from getting prostate cancer who had a history of skin cancer. However, the NPC study was conducted using a form of selenium not present in the Vitamin Products. Furthermore, two later analyses of the NPC results determined that only a small minority of men may have benefited from selenium supplementation *and* that selenium almost tripled the risk of developing diabetes: a fact which Bayer seems ignores in its advertising and labeling.
- 58. Despite the scientific evidence, and warnings by the American College of Physicians who reviewed the NPC study, Bayer does not warn that the long term use of the Vitamin Products may cause diabetes.
- 59. The selenium supplement used in the NPC trial was brewer's yeast which contained an organic form of selenium, selenomethionine.
- 60. The form of selenium contained in the Vitamin Products is listed by Bayer as sodium selenate, an inorganic form of selenium.
- 61. Research has shown selenomethionine has a significantly higher absorption rate than inorganic selenium such as sodium selenate.²³

²² http://www.oag.state.md.us/press/2009/020909.htm.

²³ Cancer Epidemiology Biomarkers and Prevention (Volume 15, pp. 804-810); American Journal of Clinical Nutrition (Volume 81, pp. 829-834, April 2005)

62. Bayer knew or should have reasonably had known that there are significant nutritional and biological differences between organic selenium, such as the selenomethionine found in brewer's yeast, and the inorganic selenium as found in the sodium selenate contained in the Vitamin Products.

CLASS ACTION ALLEGATIONS

63. Pursuant to Rules 23(b) and (c) of the Federal Rules of Civil Procedure, Plaintiff brings this lawsuit on behalf of himself and the proposed Class consisting of:

All persons who purchased the Vitamin Products in Ohio. Excluded from the Class are Defendant's officers, directors and employees and those who purchased the products for the purpose of resale.

- 64. The Class comprises thousands of consumers throughout Ohio and is therefore so numerous that joinder of all members of the Class is impracticable.
- 65. There are questions of law and fact common to the Class. The common questions include:
 - a. are the claims Bayer made and is making regarding the Vitamin Products unfair or deceptive;
 - b. is Bayer making claims that the Vitamin Products have certain performance characteristics, uses or benefits that they do not have;
 - c. is Bayer making claims that the Vitamin Products are of a particular standard, quality and/or grade, when they are not;
 - d. is Bayer supplying Vitamin Products not in accordance with its representations;
 - e. has Bayer engaged in unconscionable acts or practices in connection with a consumer transaction;
 - f. did Bayer know at the time the consumer transactions took place that the consumer would not receive the benefit from the consumer product that Bayer was claiming the consumer would receive;

- g. did Bayer knowingly make a misleading statement in connection with a consumer transaction that the consumer was likely to rely upon to his detriment;
- h. did Bayer know or should it have known that the representations and advertisements regarding the Vitamin Products were unsubstantiated, false and misleading;
- i. whether Bayer engaged in false or misleading advertising;
- j. did Bayer use deceptive representations in connection with the sale of goods;
- k. did Bayer's representations cause a likelihood of confusion or misunderstanding as to the source, sponsorship, approval or certification of goods;
- 1. did Bayer represent that goods have a certain sponsorship, approval, characteristic, ingredient, use or benefit that they do not have;
- m. did Bayer represent that goods are of a particular standard, quality or grade when they are of another;
- n. did Bayer advertise goods with intent not to sell them as advertised;
- o. did the Plaintiff and the Class members that purchased the Vitamin Products suffer monetary damages and, if so, what is the measure of said damages;
- p. whether Plaintiff and Class members are entitled to an award of punitive damages; and
- q. whether Plaintiff and Class members are entitled to declaratory and injunctive relief.
- 66. Plaintiff's claims are typical of the claims of the proposed Class.
- 67. Plaintiff will fairly and adequately represent and protect the interests of the proposed Class because, *inter alia*, Plaintiff's interests are not antagonistic to those of the Class and Plaintiff has retained counsel competent and experienced in the prosecution of this type of litigation.

- 68. The questions of law and fact common to the Class members, some of which are set forth above, predominate over any questions affecting only individual class members. The central question of whether Bayer's representations are accurate and truthful is common to all Class members and predominates over all other questions, legal and factual in this litigation.
- 69. Adjudicating this matter as a class action is superior to other available methods for adjudication because, *inter alia*, the expense and burden of requiring consumers to individually litigate these claims would make it impracticable or impossible for them to bring their claims.
- 70. This matter is manageable as a class action. Since the focus in on the Defendants' conduct, the management of this class action will be relatively easy and in all likelihood will not require complicate sub-classes or other variables that make it difficult to manage the litigation.
- 71. Unless this matter is certified as a class action, Bayer will retain the money derived from its unlawful conduct.
- 72. Bayer's unlawful conduct, including the unlawful acts described herein, and its continuing unlawful acts, are generally applicable to the Class as a whole making final injunctive relief appropriate.

FIRST CAUSE OF ACTION For Violations of Ohio Consumers Sales Practice Act, Ohio Revised Code Chapter 1345

73. Plaintiff restates each and every paragraph of this Complaint as if fully set forth herein.

- 74. This cause of action is brought pursuant to Ohio's Consumers Sales Practice Act, Ohio Revised Code § 1345, *et seq.* (the "CSPA").
 - 75. Plaintiff is a consumer as defined by Ohio Revised Code § 1345.01(D).
 - 76. Bayer is a supplier as defined by Ohio Revised Code §1345.01(C).
- 77. Bayer's conduct described herein involves consumer transactions as defined in Ohio Revised Code §1345.01(A).
- 78. Plaintiff relied upon Defendants' unsubstantiated claims in purchasing the Vitamin Products.
- 79. Bayer violated and continues to violate the CSPA by engaging in the following practices prohibited by Ohio Revised Code §1345.02 in consumer transactions with the Plaintiff and the Class, which were intended to result in, and did result in, the sale of the Vitamin Products to the Plaintiff and Putative Class:
 - (A) by "commit[ting] and unfair or deceptive act or practice in connection with a consumer transaction."
 - (B)(1) by representing that the Products have "performance characteristics...uses, or benefits that [they] do not have."
 - (B)(2) by representing that the Products are "of a particular standard, quality, grade, style, prescription…" when they are not.

* * *

- (B)(5) by representing that the Products are being "supplied in accordance with a previous representation," when they are not.
- 80. Pursuant to Ohio Adm. Code 109:4-3-10 (A) (Substantiations of Claims In Advertising) It shall be a deceptive act or practice in connection with a consumer transaction for a supplier to:

Make any representations, claims, or assertions of fact, whether orally or in writing, which would cause a reasonable consumer to believe such statements are true, unless, at the time such representations, claims, or assertions are made, the supplier possesses or relies upon a reasonable basis in fact such as factual, objective, quantifiable, clinical or scientific data or other competent and reliable evidence which substantiates such representations, claims, or assertions of fact.

- 81. In conjunction with the violations of Ohio Revised Code §1345.02 set forth above, Bayer violated Ohio Adm. Code §109:4-3-10 because it cannot and has not substantiated the advertising claims made in connection with the promotion of the Vitamin Products.
- 82. As a direct and proximate result of Defendants' violation of Ohio Revised Code § 1345.02, Plaintiff has suffered actual damages, the full amount of which will be proven at trial.
- 83. Bayer further violated and continues to violate the CSPA by engaging in the following practices proscribed by Ohio Revised Code §1345.03 in consumer transactions with the Plaintiff and the Class, which were intended to result in, and did result in, the sale of the Vitamin Products to Plaintiff and the Class:
 - (A) because Bayer has engaged and is engaging in "an unconscionable act or practice in connection with a consumer transaction;

* * *

(B)(3) because Bayer "knew at the time the consumer transaction was entered into of the inability of the consumer to receive a substantial benefit from the subject of the consumer transaction;"

* * *

- (B)(6) because Bayer "knowingly made a misleading statement of opinion on which the consumer was likely to rely to the consumer's detriment;"
- 84. Bayer violated the CSPA and Ohio Administrative Code by representing through its advertisements the Vitamin Products as described above when it knew, or should

have known, that the representations and advertisements were unsubstantiated, false and misleading.

- 85. As a direct and proximate result of Defendants' violation of Ohio Revised code §1345.03, Plaintiff has suffered actual damages, the full extent of which will be proven at trial.
- 86. Pursuant to Ohio Revised Code §1345.09(A), Plaintiff is entitled to rescind the consumer transactions or recover actual damages plus an amount not exceeding \$5,000 in non-economic damages.
- 87. Pursuant to Ohio Revised Code §1345.09(D), Plaintiff and the Class seek an order enjoining the above-described wrongful acts and practices of the Defendant and for restitution and disgorgement.
- 88. Pursuant to Section 1345.09(D), this Complaint will be served upon the Ohio Attorney General, Richard Cordray.
- 89. Plaintiff and the Class reserve the right to allege further violations of Ohio's CSPA as Bayer's conduct is ongoing.

SECOND CAUSE OF ACTION For Violations of Ohio's Deceptive Trade Practices Act Ohio Revised Code Section 4165, et seq.

- 90. Plaintiff restates each and every paragraph of this Complaint as if fully rewritten here in.
 - 91. Bayer is a person as defined in Ohio Revised Code §4165.01(D).
- 92. For the reasons discussed above, Bayer has engaged in unfair, deceptive, untrue and misleading advertising in violation of Ohio's Deceptive Trade Practices Act \$4165.02 because Bayer:

- (A)(2) "Uses [and has used in the past] deceptive representations ... in connection with goods....;
- (A)(3) "Causes likelihood of confusion or misunderstanding as to the source, sponsorship, approval, or certification of goods...."

* * *

(A)(7) "Represents that goods ...have sponsorship, approval, characteristics, ingredients, uses, benefits...that they do not have...;

* * *

(A)(9) "Represents that goods ... are of a particular standard, quality, or grade" and "they are of another";

* * *

- (A)(11) "Advertises goods ... with intent not to sell them as advertised".
- 93. Bayer's violations of Ohio's Deceptive Trade Practices Act has caused Plaintiff and the members of the Class actual damages.
- 94. Plaintiff and the Class seek actual damages and/or equitable relief and to enjoin Bayer on the terms that the Court considers reasonable.

THIRD CAUSE OF ACTION Breach of Express Warranty On Behalf of Plaintiff and the Class

- 95. Plaintiff restates each and every paragraph of this Complaint as if fully rewritten herein.
- 96. Bayer, by affirmation of fact and/or promises set forth in its promotions, advertisements and/or labeling created an express warranty that the Vitamin Products would conform to the affirmation and/or promises.

- 97. The affirmation of fact and/or promises related to the health benefits of the Vitamin Products are express warranties, became part of the basis of the bargain, and are part of a standardized contract between Plaintiff and the members of the Class and Bayer.
- 98. Plaintiff and the Class members performed all conditions precedent under the contract between the parties.
- 99. Bayer breached the terms of the express warranty between the parties including the express warranties related to the health benefits of the Vitamin Products with Plaintiff and the Class by not providing the Vitamin Products in a manner that conforms to the affirmations and/or promises.
- 100. Bayer's breach of this express warranty has directly and proximately caused the Plaintiff and the Class to suffer damages in the amount of the purchase price and the Vitamin Products.
- 101. Within a reasonable time of discovering the breach of express warranty by Bayer, Plaintiff through counsel notified Bayer of the breach of warranty. (*See* Letter of November 17, 2009 from Attorney Frank E. Piscitelli, Jr. attached as Exhibit 1.)

FOURTH CAUSE OF ACTION Breach of Implied Warranty On Behalf of Plaintiff and the Class

102. Plaintiff restates each and every paragraph of this Complaint as if fully rewritten here in. Ohio Revised Code § 1302.27 provides that unless excluded or modified, "a warranty that the goods shall be merchantable is implied in a contract for their sale if the seller is a merchant with respect to goods of that kind."

Defendants manufactured, marketed and sold the Vitamin Products and represented that the Vitamin Products were safe and fit for ordinary consumption. Contrary to such

representations, Defendants failed to disclose that the Vitamin Products were dangerous as they contained selenium.

- 103. As manufacturers, producers, marketers and sellers of dietary supplement products, Defendants are "merchants" within the meaning of the various states' commercial codes governing the implied warranty of merchantability.
- 104. The Vitamin Products are "goods," as defined by Ohio Revised Code governing the implied warranty of merchantability.
- 105. As merchants of the Vitamin Products, Defendants knew that purchasers relied upon them to design, manufacture and sell Vitamin Products that were reasonably safe and would not endanger their health.
- 106. Defendants designed, manufactured and sold Vitamin Products to consumers and they knew that such Vitamin Products would be consumed.
- 107. At the time that Defendants designed, manufactured, sold and/or distributed the Vitamin Products, Defendants knew the purpose for which the Vitamin Products were intended and impliedly warranted that the Vitamin Products were of merchantable quality and were safe and fit for their ordinary purpose dietary supplements for all persons.
- 108. Defendants breached their implied warranties in connection with their sale of Vitamin Products to Plaintiff and Class members. The Vitamin Products were not safe and fit for their ordinary purposes and intended uses as dietary supplements, and were not free of defects, such as selenium that can lead to increased risk of diabetes.
- 109. As a direct and proximate result of Defendants' breach of implied warranties, Plaintiff and other members of the Class have been injured and have suffered damages,

including, but not limited to, the value of the Vitamin Products had they been safe and fit for their ordinary purposes, and an increased risk of serious health problems.

PRAYER FOR RELIEF

Wherefore, the representative Plaintiff, on behalf of himself and the members of the putative class, prays for judgment against the Defendant as follows:

- (A) For an order certifying this action and/or common issues raised herein as a "Class Action under the appropriate provision of Federal Rule of Civil Procedure 23(a), 23(b) and 23(c); designating Class Representatives; and appointing the undersigned to serve as class counsel;
- (B) For notice of class certification and of any relief to be disseminated to all Class Members and for such other further notices as this Court deems appropriated under Fed. R. Civ. P. 23(d)(2);
- (C) For an order requiring complete and immediate disclosure of all studies, reports, analyses, data, compilations, and other similar information within the possession, custody, or control of Defendant concerning, relating to, or involving the purported health benefits of the Vitamin Products;
- (D) For an order barring Defendant from destroying or removing any computer or similar records which record evidence related to the purported health benefits of the Vitamin Products;
- (E) For an order barring Defendant from attempting, on its own or through its agents, to induce any putative Class Member to sign any document which in any way releases any of the claims of any Putative Class Member;

- (F) For an award of compensatory damages in the amount to be determined for all injuries and damages described herein;
- (G) For an award of punitive damages to the extent allowable by law, in an amount to be proven at trial;
- (H) Awarding restitution and disgorgement of Bayer's revenues to the Plaintiff and the proposed Class members;
- (I) Awarding declaratory and injunctive relief as permitted by law or equity, including: enjoining Defendant from continuing the unlawful practices as set forth herein, and directing Defendant to identify, with Court supervision, victims of its conduct and pay them, restitution and disgorgement of all monies acquired by Defendant by means of any act or practice declared by the Court to be wrongful;
- (J) Ordering Bayer to engage in a corrective advertising campaign;
- (K) Awarding attorneys' fees and costs; and
- (L) Providing such other relief as may be just and proper.

JURY DEMAND

Plaintiff demands a trial by jury on all issues so triable.

Case: 1:10-cv-00224-JG Doc #: 1 Filed: 02/02/10 27 of 27. PageID #: 27

Respectfully submitted,

/s/ Frank E. Piscitelli, Jr.

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